REMARKS

This Response is submitted in reply to the final Office Action mailed on December 20, 2007. A Petition for a one month extension of time is submitted herewith. The Director is authorized to charge $120 for the Petition for the one month extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-434 on the account statement.

Claims 1-30 are pending in this application. Claims 11-24 were previously withdrawn. In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. §112, second paragraph. Claims 1-10 and 25-30 are rejected under 35 U.S.C. §103. For the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Patent Office asserts that Claim 1 is vague and indefinite in that it is unclear whether the percentage by weight recited pertains to each of the at least one probiotic lactic acid bacterium and at least one carotenoid or to both together. See, Office Action, page 2, lines 19-21. Additionally, the Patent Office asserts that the phrase "at least one carotenoid or derivative" is not particularly defined in the specification. *Id.* at lines 22-25.

Applicants previously amended Claim 1 in the response dated October 30, 2007, to recite, in part, an orally administrable composition for the photoprotection of the skin comprising at least one carotenoid, wherein the at least one carotenoid is present in the composition in an amount from 10^{-12}% to 20% by weight. The amendment did not add new matter. The amendment was supported in the specification at, for example, page 15, lines 21-27. Therefore, Applicants previously deleted the term "derivative" and specified that it is the at least one carotenoid that is present in the composition in an amount from 10^{-12}% to 20% by weight, and not the bacterium nor the combination of the bacterium and the carotenoid. Moreover, Applicants also note that the Patent Office even recognizes that Applicants' present claims "are directed to a composition comprising '10^{-12}% to 20% by weight' of a . . . carotenoid." See,

Office Action, page 5, lines 11-14. As such, Applicants respectfully submit that one of ordinary skill in the art would understand the scope of the presently claimed subject matter.

Claim 4 is also rejected under 35 U.S.C. §112, second paragraph as being confusing for lacking antecedent basis in Claim 3 because there are several Lactobacillus and Bifidobacterium strains belonging to various species and it cannot readily be ascertained which of the deposited strains belongs to which species. See, Office Action, page 3, lines 1-5. Claim 4 was previously amended to identify the lactic acid bacteria strains of lactobacilli and bifidobacteria identified by each respective deposit number. The amendment did not add new matter and the amendment was supported in the specification at, for example, page 15, lines 1-6. Applicants also note that Claim 4 does not even depend from Claim 3 and, therefore, Claim 3 cannot lack antecedent basis for Claim 4. Based on at least these noted reasons, Applicants believe that Claims 1-10 and 25-30 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1-10 and 25-30 under 35 U.S.C. §112, second paragraph be reconsidered and the rejections be withdrawn.

In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. European Patent No. 1020123 to Vesely et al. ("*Vesely*") taken with U.S. Patent No. 6,156,355 to Shields, Jr. et al. ("*Shields*"), U.S. Patent No. 7,037,708 to Runge et al. ("*Runge*"), WO/00/070972 to Berggren et al. ("*Berggren*"), U.S. Patent No. 5,603,930 to Brassart et al. ("*Brassart*"), and further taken with U.S. Patent No. 4,806,368 to Reddy ("*Reddy*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claim 1 recites, in part, an orally administrable composition for the photoprotection of the skin comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid, wherein the at least one carotenoid is present in the composition in an amount from 10^{-12}% to 20% by weight, included in an orally acceptable carrier, the composition further comprising a yeast extract. The presently claimed oral composition includes an admixture of very specific constituents that surprisingly and unexpectedly elicit an enhanced effect or response with respect of the photoprotection of the

skin. See, Specification, page 14, lines 6-11. Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Applicants submitted herewith an Affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit A) that demonstrates the deficiencies of the prior art with respect to the present claims. Specifically, the *Affidavit* summarizes a controlled study performed by Applicants that demonstrates the surprising and unexpected synergistic photoprotective effects resulting from ingestion of the presently claimed composition comprising an admixture of a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract. As is demonstrated by the study discussed in the *Affidavit*, the presently claimed composition has been found to be effective not only for preventing inflammation or irritation of the skin after exposure to ultraviolet radiation, but it has also been found effective to provide complete prophylactic protection against the immunosuppressive effects of ultraviolet radiation. Specifically, the composition of the present disclosure is able to block or reduce the adverse clinical, histological and immunological effects of solar radiation exposure on the skin.

As is further supported by the study and *Affidavit*, it is the specific combination of the probiotic lactic acid bacterium, the at least one carotenoid, and the yeast extract that provides the surprising and unexpected synergistic photoprotective effects on the skin. For example, as is illustrated by Figure 2 of Exhibit B, the control test without UVR exposure (column 2) and the composition according to the present disclosure and having a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract (column 3) showed the greatest immunological response to the DNFB allergen, as is demonstrated by the larger differences between the swelling of the right and left ears of the mice. The increased amount of swelling of the right ear of the mice tested with respect to columns 2 and 3 indicates that the skin reacted readily to the presence of the allergen on the right ear. In other words, the skin reacted readily to the presence of the allergen on the right ear because the animal did not experience local immunosuppression due to exposure to UVR.

As is also illustrated by Figure 2 of Exhibit B, the control test plus exposure to UVR (column 1), the "matrix" formula alone plus exposure to UVR (column 4), and the carotenoids alone plus exposure to UVR (column 5) all failed to block or reduce the clinical, histological and

immunological effect of UVR exposure of the skin of the animal. These results are clearly demonstrated by the decreased amount of swelling of the right ear of the animal, which indicates that the immune system of the animal was not acting efficiently because the immune system was suppressed by the exposure to UVR. In other words, the formulas corresponding with the data of columns 1 and 4-5 proved unsuccessful in preventing local immunosuppression resulting from UVR exposure.

As such, Applicants respectfully submit that the *Affidavit* and the study discussed therein clearly demonstrates the synergistic photoprotective effects on the skin of an animal that has ingested the presently claimed composition comprising a probiotic lactic acid bacterium, at least one carotenoid and a yeast abstract. The effects of the the presently claimed composition have, thus, been compared in the study set forth in the *Affidavit* to compositions having i) only carotenoids and yeast, and ii) carotenoids alone. As such, the study and *Affidavit* clearly demonstrates the efficacy of the presently claimed composition and the importance of the combination of all three components including the probiotic lactic acid bacterium, at least one carotenoid and a yeast abstract. In contrast, Applicants respectfully submit that the cited references are deficient with respect to the presently claimed subject matter.

As further supported by the *Affidavit*, Applicants respectfully submit that the skilled artisan would have no reason to combine the cited references to obtain the present claims because the cited references are directed to unrelated products that have completely different objectives and fail to even recognize the surprising and unexpected effect that the specific composition has on the photoprotection of the skin.

For example, *Vesely* is directed toward a beverage containing live bacteria that is used to increase, balance and supplement intestinal flora. See, *Vesely*, col. 3, [0016]. *Shields* is entirely directed toward canine food formulations that optimize digestibility of nutrients in specific canine breeds. See, *Shields*, column 3, lines 30-36. *Runge* is entirely directed toward dry microorganism cultures and the processes for producing same. See, *Runge*, Abstract. *Berggren* is entirely directed toward a sports drink that is designed to increase the energy and fluid levels in an individual, as well as reduce stress. See, *Berggren*, page 2, line 39-page 3, line 4. *Brassart* is entirely directed toward a biologically pure culture of a lactic acid bacterium strain. See,

Brassart, Summary of the Invention. *Reddy* is entirely directed toward a supplement that permits the longevity of certain health promoting bacteria in tablets. See, *Reddy*, column 1, lines 10-20. As such, Applicants respectfully submit that there is absolutely no guidance in the cited reference for one of skill in the art to choose the active agents and amount of agents present in the instant claims to achieve the unexpectedly improved photoprotective effect on the skin as Applicants have done.

Moreover, in contrast to the presently claimed subject matter, and as supported in the *Affidavit*, the cited references are completely unconcerned with blocking or reducing the adverse clinical, histological and immunological effects of solar radiation exposure on the skin, as demonstrated above. Consequently, the skilled artisan would have no reason to combine the cited references to arrive at a photoprotecting composition in accordance with the present claims, nor would the skilled artisan have any reasonable expectation of success in combining the cited references. Moreover, the number of references (6) relied on by the Patent Office to support the present rejection provides evidence by itself that the present claims are not obvious. For at least the reasons discussed above, Applicants respectfully submit that Claims 1-10 and 25-30 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejections of Claims 1-10 and 25-30 under 35 U.S.C. §103 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY _____
Robert M. Barrett
Reg. No. 30,142
Customer No.: 29156
Phone No. 312-807-4204

Dated: April 18, 2008

EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Breton et al.
Appl. No.:	10/505,305
Conf. No.:	6006
Filed:	October 27, 2004
Title:	ORALLY ADMINISTRABLE COMPOSITION FOR THE PHOTOPROTECTION OF THE SKIN
Art Unit:	1651
Examiner:	I. Marx
Docket No.:	112701-434

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir: Isabelle Bureau-Franz

I hereby state as follows:

1. My experience and qualifications are as follows:

__PharmD, PhD, research coordinator. Main Scientific objective was to study how nutritional supplementation can influence beneficial effect on skin.

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein. I am also familiar with the study performed relating to the synergistic effects of the presently claimed composition and the summary of same attached as Exhibit B.

3. I have reviewed the outstanding Office Action dated December 20, 2007 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the references cited therein as well as the pending claims.

4. The present invention is directed, in part, to an oral composition that includes an admixture of very specific constituents that surprisingly and unexpectedly elicit an enhanced synergistic effect or response in respect of the photoprotection of the skin. Specifically, the present disclosure relates, in part, to a composition for the photoprotection of the skin comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract.

5. Although exposure to ultraviolet radiation may be necessary for humans to produce vitamin D, growing evidence suggests that extensive exposure to sun-light, in particular ultraviolet radiation, causes a variety of problems in the skin including, but not limited to, introduction of certain skin cancers and induction of accelerated skin aging. In addition to these established health concerns, research has also provided evidence suggesting that exposure to ultraviolet radiation may negatively affect a variety of immune responses in living beings both locally, within the UV-irradiated skin, and also systemically, *i.e.*, at sites distant from the irradiated skin.

6. With respect to the present disclosure, it has been surprisingly found that the admixture of a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract elicits an enhanced synergistic effect or response with respect to the photoprotection of the skin. The composition has been found to be effective not only for preventing inflammation or irritation of the skin after exposure to ultraviolet radiation, but it has also been found effective to provide complete prophylactic protection against the immunosuppressive effects of ultraviolet radiation. Specifically, the composition of the present disclosure is able to block or reduce the adverse clinical, histological and immunological effects of solar radiation exposure on the skin.

7. Attached hereto as Exhibit B, is a summary of a controlled study demonstrating the efficacy of the presently claimed composition with respect to the photoprotection of the skin. The study performed was a contact hypersensitivity (CHS) reaction test performed on female

hairless mice. The mice were divided into groups of ten, and four groups were used to complete one test round. Of the four groups in the test round, two groups were exposed to ultraviolet radiation (UVR) and two groups were not, as is demonstrated by the "No UVR" and "2.5 MED UVR" columns in Table 1 of Exhibit B. In each of the two different UVR exposure groups, one of the two groups therein was sensitized with the contact allergen 2,4-dinitroflurobenzene (DNFB), whereas the other group served as a control and was exposed only to acetone, as is demonstrated by the "Sensitized" and "Control" columns in Table 1 of Exhibit B.

8. Depending on the group being tested, the mice were fed a variety of formulas of food including a food with no additional supplements; a food with maltodextrin; a "matrix" food having beta-carotene, lycopene, inactivated yeast extract and excipients such as, for example, magnesium stearate, corn starch, and silicon dioxide; a food with carotenoids; and the "matrix" food that was also supplemented with a bacteria (La1). The formulas for the treatments are set forth in Table 1 of Exhibit B.

9. The mice received the respective treatments according to the scheme set out in Figure 1 of Exhibit B. The sensitization occurred about five or six days after UVR exposure by painting either DNFB or acetone on the abdomen of the animal. A challenge was performed on day 12 of the study, after UVR exposure, by painting DNFB on the right ear of the mouse and acetone on the left ear of the mouse. Figure 2 demonstrates the results of the challenge and the data is expressed as the difference between the swelling of the right ears and left ears. Blood and skin biopsies were taken at necropsy for analysis of IL-10 serum levels and epidermal LC density.

10. As is illustrated by Figure 2 of Exhibit B, the control test without UVR exposure (column 2) and the composition according to the present disclosure and having a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract (column 3) showed the greatest immunological response to the allergen, as is demonstrated by the larger differences between the swelling of the right and left ears of the mice. The increased amount of swelling of the right ear of the mice tested with respect to columns 2

and 3 indicates that the skin reacted readily to the presence of the allergen on the right ear. In other words, the skin reacted readily to the presence of the allergen on the right ear because the animal did not experience local immunosuppression due to exposure to UVR.

11. As is also illustrated by Figure 2 of Exhibit B, the control test plus exposure to UVR (column 1), the "matrix" formula alone plus exposure to UVR (column 4), and the carotenoids alone plus exposure to UVR (column 5) all failed to block or reduce the clinical, histological and immunological effect of UVR exposure of the skin of the animal. This is clearly demonstrated by the decreased amount of swelling of the right ear of the animal, which indicates that the immune system of the animal was not acting efficiently in response to the presence of the allergen after exposure to UVR. In other words, the formulas corresponding with the data of columns 1 and 4-5 proved unsuccessful in preventing local immunosuppression resulting from UVR exposure.

12. With respect to the cited references, the skilled artisan would have no reason to combine the cited references to obtain the present claims because the cited references are directed to unrelated products that have completely different objectives and fail to even recognize the surprising and unexpected effect that the specific composition has on the photoprotection of the skin, as is clearly demonstrated by the results of the study attached as Exhibit B.

13. *Vesely* is directed toward a beverage containing live bacteria that is used to increase, balance and supplement intestinal flora. See, *Vesely*, col. 3, [0016]. *Shields* is entirely directed toward canine food formulations that optimize digestibility of nutrients in specific canine breeds. See, *Shields*, column 3, lines 30-36. *Runge* is entirely directed toward dry microorganism cultures and the processes for producing same. See, *Runge*, Abstract. *Berggren* is entirely directed toward a sports drink that is designed to increase the energy and fluid levels in an individual, as well as reduce stress. See, *Berggren*, page 2, line 39-page 3, line 4. *Brassart* is entirely directed toward a biologically pure culture of a lactic acid bacterium strain. See, *Brassart*, Summary of the Invention. *Reddy* is entirely directed toward a supplement that permits

the longevity of certain health promoting bacteria in tablets. See, *Reddy*, column 1, lines 10-20. As such, there is absolutely no guidance in the cited references for one of skill in the art to choose the active agents and amount of agents present in the instant claims to achieve the unexpectedly improved photoprotective effect on the skin as Applicants have demonstrated in the present disclosure and in the summary of the study attached as Exhibit B.

14. In contrast to the presently claimed subject matter, the cited references are completely unconcerned with blocking or reducing the adverse clinical, histological and immunological effects of solar radiation exposure on the skin, as demonstrated above and in Exhibit B. Consequently, the skilled artisan would have no reason to combine the cited references to arrive at a photoprotecting composition in accordance with the present claims, nor would the skilled artisan have any reasonable expectation of success in combining the cited references.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date:_____April, 8th, 2008

_____ _____

Print Name ____Isabelle Bureau-Franz

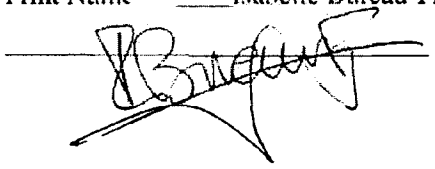


EXHIBIT B

METHODS AND MATERIALS

This study was conducted by Nestec S.A. at the Centre International de Toxicologie (CIT) in Evreux, France.

The study consisted of a contact hypersensitivity (CHS) reaction test in female hairless Skh:hr1 mice. Ten mice were randomly assigned to each treatment group. One test consisted of four treatment groups, as is demonstrated by the rows of Table 1 below. Two of the four treatment groups were not exposed to any ultraviolet radiation (UVR), and two of the four treatments groups were exposed to 2.5 MED solar-simulated UVR, as is demonstrated by the designations "No UVR" and "2.5 MED UVR" in Table 1 below. In each of the two different UVR exposure groups, one of the two groups therein was sensitized with the contact allergen 2,4-dinitroflurobenzene (DNFB), whereas the other group served as a control and was exposed only to acetone, as is demonstrated by the "Sensitized" and "Control" columns in Table 1 below.

Table 1
Formulations Tested

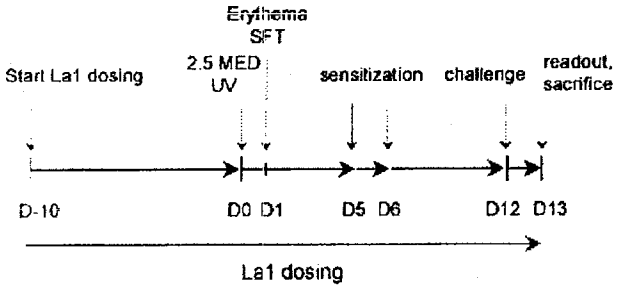
Supplementation	No UVR		2.5 MED UVR	
	Control	**Sensitized**	**Control**	**Sensitized**
No treatment	Group 1	Group 2	Group 3	Group 4
Maltodextrin	Group 5	Group 6	Group 7	Group 8
Matrix*	Group 27	Group 28	Group 29	Group 30
Carotenoids	Group 31	Group 32	Group 33	Group 34
Matrix* + La1 10^8 cfu/d**	Group 35	Group 36	Group 37	Group 38

* The matrix consisted of beta-carotene, lycopene, inactivated yeast extract, and excipients (magnesium stearate, corn starch and silicon dioxide). The carotenoid preparation was composed as the matrix without the yeast extract.
** Bacterial inactivation was by γ-irradiation at 41 kGy (Studer AG,Däniken).

The matrix components for the study were from SIIT, Italy. The formulations were mixed under nitrogen and packed under an inert atmosphere, shipped on dry ice and stored at 4°C.

The animals received the respective treatments according to the treatment scheme shown below in Figure 1.

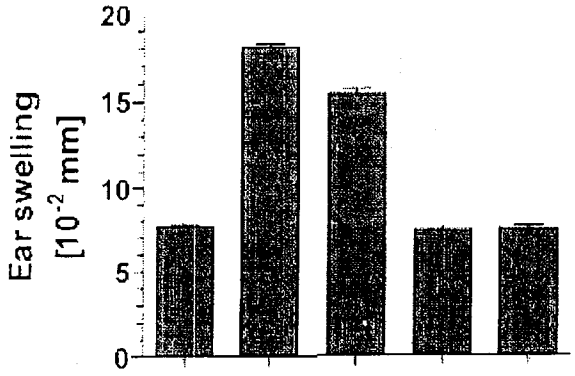
Figure 1
Animal Treatment Scheme



The sensitization occurred five and six days after UVR exposure by painting either DNFB or acetone on the abdomen of the mice. A challenge was performed on day 12 after UVR exposure by painting DNFB on the right ears and acetone on the left ears of the animals. The data of Figure 2 below is expressed as the difference between right and left ear swelling, measured in millimeters. Blood and skin biopsies were also taken at necropsy for analysis of IL-10 serum levels and epidermal LC density.

RESULTS AND CONCLUSIONS

Figure 2
Results of the Tests



Column 1 - Control +UV
Column 2 - **Control without UV**
Column 3 - Matrix + La1 10^8 live + UV = **composition according to the invention**
Column 4 - Matrix alone +UV
Column 5 - Carotenoids alone +UV

Figure 1 demonstrates the lack of a photoprotective effect of the matrix (carotenoids and yeast) alone, and carotenoids alone, as is shown by columns 4 and 5. Figure 1 also demonstrates the effect of La1 plus the matrix on CHS reaction, as is shown by column 3. The data resulting from the presence of La1 10^8 cfu in the matrix was significantly different than the data resulting from the control +UV ($p<0.001$).

Thus, it has been shown that the matrix alone (column 4) or the carotenoids alone (column 5) had no photoprotective effect on UVR-induced immunosuppression ($p>0.05$ relative to control +UV). Instead, a photoprotective effect on UVR-induced immunosuppression was observed only for the tests involving the matrix (carotenoids and yeast) plus La1.